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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,073

02/18/2004

Aiden Flanagan

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EXAMINER

SELLMAN, CACHET I

ART UNIT

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1792

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/782,073	<b>Applicant(s)</b> FLANAGAN, AIDEN	
	<b>Examiner</b> CACHET I. SELLMAN	<b>Art Unit</b> 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 24-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 12-23 is/are rejected.
- 7) ☒ Claim(s) 2,12 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/26/2005, 7/13/2005, 2/18/2004</u> .                       | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-24 in the reply filed on 2/12/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 10-24 been renumbered 9-23 respectively.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Merdan et al. (US 6440503).

Merdan et al. teaches a process for coating medical devices using a laser beam. The process comprises arranging on the surface of a substrate, carrier (30), a solution (a sacrificial layer (37); directing a beam at the substrate (44); and arranging the device in an ejection cone formed by a vaporization of solution (see col. 6, lines 32-49) as required by **claim 1**. The beam is a laser (see abstract) as required by **claim 13**. The substrate can be moved relative to the beam (see abstract) as required by **claim 16**.

6. Claims 1, 4-5, 10, and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chrisey et al. (US 6766764).

Chrisey et al. discloses a process for depositing a transfer material onto a receiving substrate using a source of pulsed laser energy. The process comprises arranging on the surface of a substrate (15 of Fig. 1) a solution, wherein the solution is a matrix material with a transfer material (see col. 7, lines 30-55 and col. 9, lines 1-15 and 16 of Fig. 16); a beam (14 of Fig. 1) is directed at the substrate and heats the substrate; and the device being coated (receiving substrate) is placed in an ejection cone formed by a vaporization of the solution. The matrix material of the solution vaporizes which allows the transfer material to coat the receiving substrate (see abstract, col. 6, lines 50-66) as required by **claim 1**. The solution includes a bioactive agent (see col. 5, line 65 – col.6,line 4) dissolved in a solvent, where the solvent volatilizes and the bioactive agent (transfer material) is not vaporized or melted therefore the solvent has a lower boiling point than the thermal damage temperature of the bioactive agent (see col. 6, line 55-

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65, col. 9, line 1-15) as required by **claim 4**. The bioactive agent, transfer material, is ejected or propelled to the object due to the vaporization of the solvent (see Fig. 2b, abstract, and col. 7, lines 47-55) as required by **claim 5**. The solution is applied by spin coating (see col. 9, line 19) as required by **claim 10**. The substrate can be planar (see col. 9, line 43) as required by **claim 12**. The beam is a laser pulsed laser beam (see col. 9, line 9 - col. 10, line 14) as required by **claims 13-14**. The beam can be moved with respect to the substrate or the substrate can be moved with respect to the beam (see col. 10, lines 15-20) as required by **claims 15-16**. The receiving substrate can be a biological sensor as required by **claim 17**.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 3-9, 10, 12-20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talton (US 2006/0051522) in view of Chrisey et al.

Talton discloses a process for coating a surface or performing a surface modification on a device. The process comprises providing a target material such as a matrix target which is heated with a laser and ablates into a dense plume of atomic clusters which are deposited onto the device (0046). The matrix target comprises of biocompatible or biodegradable materials. The matrix target can be in liquid or solid form (0047). The device which is coated can be a biomedical device such as a stent (see 0019). Talton states that a gas flow is used to help direct the ablated material to the device being coated (see 0015). Talton states that drugs, proteins or bioactive ceramics can be incorporated which can further modify a desired biological response. Talton states that the rate of diffusion and or release of an active component can be modified by producing different compositions (see 0036).

Taton fails to teach that the liquid is placed on a substrate. However, it would have been obvious to one having ordinary skill in the art to use a substrate to hold the matrix during the laser process especially if the matrix is in the form of a liquid and Chrisey et al. teaches a similar process where the matrix is placed on a substrate while being treated with laser and transferred to the receiving substrate.

The solution is vaporized and atomized as shown in (0046) as required by **claim 3**. The solution includes a bioactive agent (see col. 5, line 65 – col.6,line 4) dissolved in a solvent, where the solvent volatizes and the bioactive agent (transfer material) is not vaporized or melted therefore the solvent has a lower boiling point than the thermal damage temperature of the bioactive agent (see col. 6, line 55-65, col. 9,line 1-15) as required by **claim 4**. A bioactive agent is ejected into the zone (see 0046) as required

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by **claim 5**. The bioactive agent includes a drug and polymer (see 0036) as required by **claim 6**. A gas flow is used to direct the agent to the device (see 0015) as required by **claim 7**.

In regards of **claims 8 and 9**,

The substrate and device are enclosed and the solvent is removed by the use of a valve. However, it is well known in the art to use a vacuum pump to evacuate vaporized materials from a chamber therefore one would have a reasonable expectation of success in removing the solvent from the chamber when using a pump. The solution is applied by spin coating (see col. 9, line 19) as required by **claims 10 and 20**. The substrate can be planar (see col. 9, line 43) as required by **claim 12**. The beam used is a pulsed laser (see 0056) as required by **claims 13-14**. The beam can be moved with respect to the substrate or the substrate can be moved with respect to the beam (see col. 10, lines 15-20) as required by **claims 15-16**. The medical device can be a stent (see 0019) as required by **claims 17-18**.

In regards to **claims 19, 22 and 23**,

it would have been obvious to one having ordinary skill in the art at the time the invention was made to use another solution with a different agent in order to produce a medical device such as a stent, with varying delivery rate of different agents in order to properly treat a patient (see 0036). In order to provide such a controlled release the solvents of each of the solutions would have differing boiling points in order to optimize such delivery rates of the different drugs.

***Allowable Subject Matter***

10. Claims 2, 11, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The prior art fails to teach processes where the solution does not absorb any of the beam or where the substrate holding the solution transfer heat to the solution to vaporize the solution.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman  
Examiner  
Art Unit 1792

/C. I. S./  
Examiner, Art Unit 1792

/William Phillip Fletcher III/  
for Timothy H. Meeks, SPE of Art Unit 1792/1700